-- One hundred and ninety-two serum samples and 56 spotted urine samples were used. After these samples were appropriately diluted with the blocking solution, L-PGDS concentrations were determined by the sandwich ELISA as described above. The results of the assay revealed that the mean value± standard deviation of serum L-PGDS concentration obtained from healthy subjects was 0.848 ± 0.186 μg/ml. In the analysis using spotted urine samples, the determined values were converted into urinary L-PGDS indexes (L-PGDS/g creatinine) using urinary creatinine concentrations, considering influences of the difference in urinary concentrations depending on the time of sampling. As a result, the mean value ± standard deviation of urinary L-PGDS index obtained from healthy subjects was 2.44 ± 1.86 mg/g creatinine. From the thus obtained mean value ± standard deviation, a reference value was set according to the formula described earlier, i.e. the mean value + (2 x standard deviation). The reference value for serum L-PGDS concentration was 1.22 μg/ml and the reference value for urinary L-PGDS index was 6.16 mg/g creatinine. --

In the claims:

Please amend claims 1, 2, 4 to 7 and 9 to 12 as follows (claims not amended are shown in bold, small face type for reference purposes only):

-- 1. (Amended) A method of detection of an early-stage renal disease, comprising:

determining the concentration of human lipocalin-type prostaglandin D synthase in a body fluid sample taken from a subject who substantially appears not to have any renal diseases; and

comparing the determined concentration with a reference value set by determining the concentrations of human lipocalin-type prostaglandin D synthase in body fluid samples taken from healthy subjects.

2. (Amended) A method of monitoring a progression of a renal disease, comprising:

determining the concentration of human lipocalin-type prostaglandin D synthase in a body fluid sample taken from a subject; and

B3 Contd. evaluating a glomerular filtration activity of the subject from the determined concentration.

3. The method of claim 1, wherein the determination of the concentration of human lipocalin-type prostaglandin D synthase in a body fluid sample is performed by an immunological assay method.

4. (Amended) The method of any one of claims 1 to 3, wherein the renal disease causes glomerular lesions.

5. (Amended) The method of any one of claims 1 to 3, wherein the renal disease is caused by hypertension or lipid metabolic disorder.

B4 6. (Twice Amended) The method claim 18, wherein the renal disease comprises nephropathy.

7. (Amended) The method of claim 18, wherein the renal disease comprises glomerulonephritis, nephrotic syndrome, diabetic nephropathy, nephrosclerosis, polycystic kidney or renal failure.

8. The method of claim 2, wherein the determination of the concentration of human lipocalin-type prostaglandin D synthase in a body fluid sample is performed by an immunological assay method.

9. (Amended) The method of claim 8, wherein the renal disease causes glomerular lesions.

B5 Contd. 10. (Amended) The method of claim 8, wherein the renal disease is caused by hypertension or lipid metabolic disorder.

11. (Amended) The method of claim 19, wherein the renal disease comprises nephropathy.

B Cont'd.

12. (Amended) The method of claim 19, wherein the renal disease comprises glomerulonephritis, nephrotic syndrome, diabetic nephropathy, nephrosclerosis, polycystic kidney or renal failure.--

Please add claim 13 to 20.

-- 13. (New) A method of detecting early-stage renal abnormality comprising:

determining a concentration of human lipocalin-type prostaglandin D synthase in a body fluid sample of a subject who is substantially asymptomatic of renal diseases; and

comparing the concentration determined with a reference value set by determining the concentrations of human lipocalin-type prostaglandin D synthase in body fluid samples of healthy subjects.

14. (New) A method of monitoring a progression of renal abnormality comprising:

determining a concentration of human lipocalin-type prostaglandin D synthase in a body fluid sample of a subject; and

correlating the determined concentration of human lipocalin-type prostaglandin D synthase with glomerular filtration function.

B Cont'd.

15. (New) The method of claim 13, wherein the determination of the concentration of human lipocalin-type prostaglandin D synthase in a body fluid sample is performed by an immunological assay method.

16. (New) The method of any one of claims 13 to 15, wherein the renal abnormality causes glomerular lesions.

17. (New) The method of any one of claims 13 to 15, wherein the renal ambormality ia caused by hypertension or lipid metabolic disorder.

18. (New) A method of determining whether an individual is at risk for a renal disease at an early stage of the renal disease, comprising:

determining a concentration of human lipocalin-type prostaglandin D synthase in a body fluid sample of a subject who is substantially asymptomatic of any renal diseases; and

comparing the concentration determined with a reference value set by determining the concentrations of human lipocalin-type prostaglandin D synthase in body fluid samples of healthy subjects, wherein the concentration is determined by enzyme-linked immunosorbent assay.

19. (New) A method of determining whether an individual is at risk for a renal disease at an early stage of the renal disease, comprising:

providing a body fluid sample of an individual who is substantially asymptomatic of any renal diseases; and

comparing the level of human lipocalin-type prostaglandin D synthase in the body fluid sample of the individual to the level of human lipocalin-type prostaglandin D synthase in a control sample from a healthy individual, wherein a higher level in the sample from the individual is an indication that the individual is at risk for developing a renal disease.

20. (New) A method of determining whether an individual is at risk for nephropathy at pre-nephropathic stage of the renal disease, comprising:

providing a body fluid sample of an individual who is substantially asymptomatic of any renal diseases; and

comparing the level of human lipocalin-type prostaglandin D synthase in the body fluid sample of the individual to the level of human lipocalin-type prostaglandin D synthase in a control sample from a healthy individual, wherein a higher level in the sample from the individual is an indication that the individual is at risk for developing a renal disease. --